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Research Article

Design Formulation And Evaluation Of Anti Migraine Mouth Dissolving Tablets Using Different Superdisintegrants

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ABSTRACT

Through the application of novel approaches to the administration of medication, the purpose of this study is to enhance the safety, efficacy, and rate of action of the existing molecule. Orally disintegrating pills containing rizatriptan benzoate were manufactured by the direct compression process in order to provide migraine sufferers with a more expedient means of obtaining relief. A 32-factororial design approach was utilized in this investigation, and eight distinct formulations were evaluated for each of the super disintegrants that were investigated. The created batches of tablets were subjected to a series of examinations, including weight variation, hardness, friability, wetting time, invitro dispersion time, drug content, and invitro dissolution. In order to determine the dose form of Rizatriptan Benzoate tablets, a UV spectrophotometric method that is uncomplicated, sensitive, rapid, accurate, cost-effective, and repeatable was developed. At a wavelength of 225 nm, rizatriptan benzoate exhibits the highest absorbance, and its molar absorption is measured at 1.619 Ao. The application of Beer's law was seen between 1 and 10 µg/ml. The findings of the analysis were validated by conducting statistical analysis and recovery studies. In order to validate the method, several different criteria were utilised, including linearity, accuracy, limit of detection (LOD), limit of quantification (LOQ), Sandell's sensitivity, and specificity. Through the use of the recommended method, it was discovered that the procedure of estimating the regular dosage of Rizatriptan Benzoate in both tablet and bulk forms is one that is accurate and precise. The optimised formulation took between fifteen and thirty seconds to spread throughout the body. In addition to this, it displayed a higher water absorption ratio and also released 99.60% of the medicine over a period of two minutes and fifteen seconds.

Key Words: Rizatriptan, LOQ, LOD, ODDS

Introduction

Oral administration is by far the most common and favoured mode of drug delivery, regardless of whether the medication is administered in solid or liquid form. Solid dosage forms, on the other hand, are popular because of the numerous benefits they offer, which include patient compliance, the avoidance of discomfort,

the convenience of administration, and precise dosing for self-medication (1). Tablets and capsules are the most common forms of solid dosage forms presently available. To put that into perspective, a significant number of people have difficulty swallowing tablets or capsules made of firm gelatin (2). It has been noted that this problem occurs across all patient demographics; however, it is more widespread in the populations of children and the elderly. As a consequence of this, typical dose forms result in a high percentage of noncompliance and ineffective swallowing therapy, particularly in situations involving toddlers, the elderly, or people who have developed mental retardation (3). Just a few of its many advantages include its stability, the fact that it may be administered without the use of water, its exact dosing, its ease of manufacture, its small packaging, and its handling (4). Due to the ease with which it can be administered, this specific dose type is highly common, particularly among groups that are either mentally challenged, elderly, or children. The use of superdisintegrants enables rapid dissolving, which in turn enables rapid absorption of the medication and, ultimately, a prompt onset of the effects of the medication (5). Rizitriptan has a bioavailability of 45% when taken orally, which is a very high percentage. The standard tablet and the oral dosing tablet (ODT) both have half-lives that range from two to three hours and Tmaxes that are one and a half hours, with the ODT taking somewhat longer. One hundred milligrammes of sumatriptan is comparable to ten milligrammes of rizatriptan benzoate when consumed as a typical anti-migraine medication. The anti-migraine medicine rizatriptan benzoate, which is a more recent generation of triptans, is superior to prior generations of triptans when it comes to treating acute migraine attacks [1]. Specifically, it is a 5-hydroxytryptamine1B/1D receptor agonist that is both powerful and selective. The chemical formula for this compound is 3-[2-(dimethylamino) ethyl]monobenzoate of 5-(1H-1,2,4-triazol-1-ylmethyl)indole. One dose of rizatriptan benzoate, which is an alternative to the more conventional treatment for migraines known as sumatriptan, is comparable to one hundred milligrammes of sumatriptan [2]. Comparatively, the bioavailability of rizatriptan benzoate is approximately 45%, which is significantly higher than the bioavailability of sumatriptan, which is just 14–17%. It is possible that you will begin to feel the effects of the migraine medicine, which will help to alleviate your discomfort, within an hour of taking it [1]. Because of the severe reduction in their functional abilities, people who suffer from migraines would benefit from acute treatment that enables them to resume functional activities as quickly as feasible. Patients who have difficulty swallowing or digesting solid dose forms, who are immobile, who feel nauseated, or who do not comply with their treatment can now take advantage of certain effective alternatives to solid dosage forms, which have become available as a result of technical improvements [3, 4]. Because of this, they are an excellent choice for pills that dissolve in the mouth or otherwise disintegrate. Through the acceleration of the drug's release into the bloodstream, the incorporation of superdisintegrants into the formulation results in an increase in the drug's bioavailability [5]. Due to the fact that the drug-containing tablet dissolves instantly in saliva when it is taken orally, it is possible to swallow the medicine orally as a liquid without the need for water [3, 6, 7]. This dose form is appropriate for use in settings when running water is not easily available, such as when travelling [3]. Because of its portability, it is ideal for usage in scenarios like these. In addition, this dosage form is a combination of the most advantageous aspects of both the liquid and tablet forms. By way of the mouth, throat, and pharynx, saliva makes its way to the stomach, which is the location where certain drugs are absorbed. Under these conditions, the bioavailability of the medication is significantly higher than what is seen when the medication is administered in the form of common tablets. Patient non-compliance is substantially eliminated by this method of drug delivery, which enables patients of all ages, including children, the elderly, and the general community, to take their medications in a quiet manner wherever and whenever they are required to do so. The advantages that these tablets offer in terms of patient compliance, rapid initiation of action, higher bioavailability, and high stability have contributed to their popularity as a dosage form of choice in the current market [8,9].

The bioavailability of Rizatriptan benzoate is approximately 45%, which is significantly higher than the low bioavailability of Sumatriptan, which ranges between 14-17% (6,7). The freeze-dried dosage form of Rizatriptan is available on the market, which enables the drug to be broken down more quickly. One of the most significant drawbacks of this technology is that it is quite expensive, the procedure is not feasible, and the product is extremely vulnerable to moisture. Drying in the freezer is a challenging process that results in a product that is both fragile and hygroscopic (8). Superdisintegrants that are naturally occurring were utilised in this work. Because natural superdisintegrants are safer, more biodegradable, better compressible, quicker to prepare, and more affordable, the production of organic dispersive materials (ODTs) can be improved as a result of these and other benefits (9). For the purpose of this experiment, the tablets that dissolve quickly were produced by the process of direct compression, with a number of different pharmaceutical excipients being utilised each time. Avicel pH 102, crospovidone, Plantago ovata mucilage, mannitol, aspartame, aerosil, and magnesium stearate were the excipients that were employed in this formulation.

Material & Methods

A complimentary sample of Rizatriptan Benzoate was made available by Cipla Ltd. in Kurkumbh, Pune. Indion 234 was the sample that was provided by Wyeth Ltd., which is located in Verna, Goa. The Indion 414 was given as a gift by Ion exchange (India) Ltd., which is located in Mumbai. Arihant Trading Co., which has

its headquarters in Mumbai, was the supplier of the carboxymethylcellulose calcium. Aspartame, mannitol, magnesium stearate, crospovidone, and avicel PH-102 were all ingredients that were provided by Glenmark Pharmaceuticals Ltd., which is located in Colvale, Goa. Simply put, we only used chemicals of an analytical grade for everything else.

Preparation of oral disintegration tablets

For the production of Rizatriptan pills that disintegrate when taken orally, the direct compression method was utilised. To separate each component, a sieve with a mesh size of sixty was utilised. All of the following components were mixed together with the help of a mortar and pestle: rizatriptan, crospovidone, psyllium mucilage, avicel PH 102, mannitol, and aspartame. For the purpose of lubricating the mixtures, one percent aerosol had been combined with one percent magnesium stearate. After being prepped for compression, the mixes were then turned into tablets so that they could be compressed. A tablet machine (ErwekaAR 4100, Germany) equipped with a flat round punch of 3 millimetres in diameter was utilised in order to crush the tablets. The experimental factorial design compositions were presented in Table 1.

Evaluation of mixed powder blend of drug and excipients

Every single formulation was put through a series of tests to determine its angle of repose, bulk density, tapped density, Hausner's ratio, and Carr's index, in addition to being evaluated for drug and excipient preparations.

Bulk and tapped density

Two densities were measured: the bulk density and the tapped bulk density. A 10-milliliter measuring cylinder was filled with an appropriate amount of powder from each recipe. This was done after gently stirring the powder to remove any clumps that may have developed. After the initial volume was measured, the cylinder was dropped from a height of 2.5 cm onto a hard surface at two second intervals. It was permitted that the cylinder should collapse due to its own weight. After the output volume stopped changing noticeably, tapping was stopped. Two density computations were performed: the bulk density and the tapped bulk density.

Table: 1 COMPOSITION OF DIFFERENT BATCHES OF MOUTH DISINTEGRATING TABLETS OF RIZATRIPTAN BENZOATE

Ingredients	F_1	F_2	F_3	F_4	F_5	F_6	F_7	F_8	F_9
Rizatriptan benzoate	10	10	10	10	10	10	10	10	10
Crospovidone	3	6	9	3	6	9	3	6	9
Psyllium mucilage	6	6	6	9	9	9	12	12	12
Aerosil	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5
Magnesium stearate	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5
Aspartame	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5
Avicel PH 102 up to	150	150	150	150	150	150	150	150	150

Carr's index

Through the utilisation of Carr's index, the compressibility index of the powder blend was determined. The Db and Dt values of a powder, in addition to the packing down rate, can be simply evaluated with the help of this basic test. To calculate Carr's Index, the formula is as follows:

$$Carr\ index = \frac{D_t - D_b}{D_t} \times 100$$

Where Dt is tapped density of the powder and Db is bulk density of the powder.

Hausner ratio

The formula for Hausner's ratio was determined by comparing the bulk and tapped densities of the Rizatriptan blend powder:

$$Hausner's\ ratio = \frac{D_t}{D_t}$$

Where D_t is tapped density and D_b is bulk density.

Angle of repose

The fixed funnel method was used to determine the angle of repose (θ). The funnel's height was set such that its tip barely touched the top of the granules pile. Without restriction, the granules were let to pour out of the

funnel and land on the ground. Using the following formula, we were able to determine the granular cone's diameter and angle of repose:

$$\tan\theta = \frac{h}{r}$$

Evaluation of disintegration tablets

Weight variation

Code	Angle of repose (θ)	Bulk density (gr/cm³)	Tapped density (gr/cm³)	Carr's index (I)	Hausner's ratio
F_1	31.4±0.02	0.37±0.06	0.41±0.02	10.15±1.13	1.11
F_2	31±0.03	0.32±0.07	0.35±0.02	09.10±1.01	1.10
F_3	30.6±0.02	0.34±0.04	0.37±0.02	07.94±0.35	1.08
F_4	30.1±.003	0.36±0.02	0.39±0.02	06.63±1.27	1.07
F_5	30.3±0.01	0.33±0.03	0.36±0.02	09.53±1.05	1.10
F_6	29.4±0.05	0.35±0.04	0.39±0.01	09.53±1.11	1,10
F_7	29±0.02	0.36±0.07	0.39±0.01	07.08±1.36	1.07
F_8	29.4±0.01	0.37±0.05	0.43±0.01	14.75±1.55	1.17
F_9	28.9±0.03	0.34±0.07	0.37±0.02	07.94±0.35	1.08

F: formulation

Tablet thickness

The thickness was measured by placing tablet between two arms of the Vernier calipers. 5 tablets were taken and their thickness was measured.

Tablet hardness

The force needed to break a tablet is proportional to the square of its diameter; this is the hardness of the tablet. The erweka Hardness Tester (16) was used to determine the tablets' hardness through diametral compression.

Friability Testing

In order to determine the impact that shock and friction would have, we conducted this experiment. In the Erweka friabilator, ten tablets that had been weighed in the past were spun at a speed of twenty-five revolutions per minute for approximately four minutes. Following the dedusting process, the tablets were reweighed in order to ascertain the percentage of their friability. When it comes to compressed pills, a weight loss of less than one percent is considered acceptable (17).

$$Percentage\ friability = \frac{Initial\ weight - Final\ weight}{Initial\ weight} \times 100$$

Wetting time

For the purpose of determining how long it took for the pills to become wet, a straightforward procedure was utilised. Five tissue papers with a diameter of ten centimetres each were placed inside of a petridish that had a diameter of ten centimetres. In a volume of ten millilitres of water, a dye that is water-soluble and is known as eosin was added to the petridish. The surface of the tissue paper was covered with a tablet in a very delicate manner. The wetting time was considered to be a measurement of the amount of time it took for water to reach the top surface of the tablets. The lengths of time that the area was wet were recorded (18).

Water absorption ratio

The contents of a small petri dish with an interior diameter of 6.5 centimetres were filled with 6 millilitres of water, and a piece of tissue paper that had been folded twice was placed within the little dish. When a tablet was placed on the paper, the amount of time it took for the tablet to become totally saturated with water was then recorded. This equation was utilised in order to ascertain the water absorption ratio, which is denoted by the letter R.

$$R = \frac{W_a - W_b}{W_a} \times 100$$

Invitro disintegration test

The in vitro disintegration experiments were carried out with the assistance of a computerised tablet disintegration test device manufactured by Erweka ZT out of Germany. The basket assembly was constructed with six tubes, and each of those tubes was initially filled with one tablet. After that, a disc was placed inside

of each tube. Next, the combination was maintained at a constant temperature of 37±2 degrees Celsius while it was suspended in a beaker that contained water and had a capacity of one litre. A pace of 28 to 32 cycles per minute was then used to lower and raise the basket by a distance of 5 to 6 centimetres each minute. The amount of time that was required for the tablet to completely dissolve was recorded as twenty.

Dissolution test

For the purpose of determining the rate at which Rizatriptan benzoate was released from orally dissolving tablets, we utilised the paddle method, which is described in the United States Pharmacopoeia (USP) XXIV dissolution testing equipment II. A dissolution test was conducted at 37±0.5 ºC and 50 rpm, with 900 ml of 0.1N HCl with a pH of 1.2. The temperature was maintained at 37±0.5 ºC. After one, two, three, four, five, ten, twenty, and thirty minutes, a five-milliliter sample of the solution was exhausted from the apparatus used for dissolving. For the purpose of filtering the samples, a 0.45 membrane filter was utilised. For the purpose of determining the absorbance of the solutions at 280 nm, a Shimadzu spectrophotometer was utilised. In order to generate an equation that was utilised to estimate the cumulative proportion of medicine release, a standard curve was utilised.

Content uniformity

Before being turned into powder, each batch's 10 pills were measured and then ground. After measuring out an exact quantity of 5 milligrammes (mg) of this Rizatriptan benzoate powder, it was combined with approximately 50 millilitres (ml) of 0.1 N hydrochloric acid and then shaken for a period of fifteen minutes. via the addition of 0.1 N hydrochloric acid and the subsequent filtration of the mixture via Whatmann No. 1 filter paper, a final volume of 100 ml was accomplished. Ten millilitres of this were used to create a solution that was one hundred millilitres in volume. The final volume was obtained by diluting 2 millilitres of the solution described above with 10 millilitres of 0.1 N hydrochloric acid. Through the utilisation of a UV/Vis spectrophotometer, the absorbance of the solution was determined at 280 nm in comparison to a blank for the reagent itself. On the other hand, the content was evaluated by means of a calibration curve that had been developed by employing standard Rizatriptan benzoate in the same medium (see to Table 3 for more information). The mean percent of drug content was calculated by taking the average of the three measurements and calculating the average.

Table: 3 Evaluation of the prepared orodispersible tablets of Rizatriptan

Tests	F_1	F_2	F_3	F_4	F_5	F_6	F_7	F_8	F_9
Weight variation (Mean±SD)	151±3.45	149±2.24	149±3.12	150±3.71	152±3.32	148±1.58	147±3.28	151±3.45	149±2.24
Hardness (kg/cm²)	3.81±0.25	3±0.27	3.8±0.22	3.8±.023	3.7±0.27	3.1±0.19	3.7±0.22	3±0.23	3.2±0.21
Friability	0.57±0.16	0.68±0.14	0.81±0.15	0.93±0.147	0.96±0.157	0.72±0.155	0.44±0.138	0.80±0.149	0.66±0.153
Thickness (mm)	3.2	2.9	3.00	3.1	3.1	3.2	2.9	3.3	3.4
Wetting time (s)	62	59	51	49	44	41	40	30	33
Water absorption ratio	78.12	80.25	82.34	85.74	86.64	88.57	90.47	93	91
In-vitro disintegration time (s)	56	54	48	45	41	37	32	27	30
Assay	98.3	97.2	98.7	96.7	98.2	95.8	99.4	97.2	97.3

F: formulation

Result & Discussion

A. Pre formulation Study

Characterization of Rizatriptan Benzoate

Organoleptic properties:

Melting point:

The melting point of Rizatriptan benzoate was foundto be in the range of 179° to 181°C.

Determination of saturation solubility:

Rizatriptan benzoate's solubility in various solutions is shown in Table 5. These solutions include deaerated water, buffer pH 6.8, and 0.1 N hydrochloric acid. When comparing deaerated water, 0.1 N HCl, and buffer pH 6.8, the drug's solubility is higher in the former.

Table 4: Solubility Data of Rizatriptan Benzoate

Solvent	Solubility (mg/mL)
0.1 N HCl	43.42
Diaurated water	219.98
Buffer pH 6.8	50.12

UV spectroscopy (Determination of λ max):- Wavelength of maximum absorbance (λ max) of Rizatriptan benzoate was found to be 225 nm in deaerated water (Figure 1).

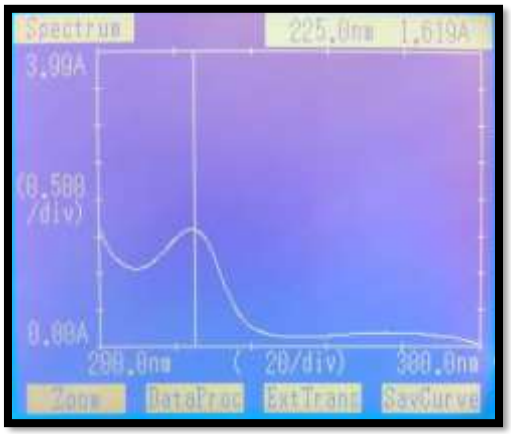

Figure (1): UV Spectra of Rizatriptan Benzoate(λmax.).

Calibration Curve for Rizatriptan Benzoate:- Figure 2 and Table 4 present the calibration curve for rizatriptan benzoate when it is used in deionized water.Within the concentration range of 1-10 µg/ml, rizatriptan benzoate demonstrated a linear connection between absorbance and concentration at 225 nm. this relationship was seen. A value of 0.999 for the R2 of the calibration curve indicates that it adheres to the Beers Lambert law, at least within the concentration range that is being considered.

Table 5 Calibration curve of RizatriptanBenzoate

Sr. no.	Concentration (µg/ml)	Absorbance at 225nm
1	0	0
2	1	0.2763
3	2	0.4676
4	3	0.7083
5	4	0.9149
6	5	1.1441
7	6	1.3439
8	7	1.5565
9	8	1.8086
10	9	2.0412
11	10	2.2827

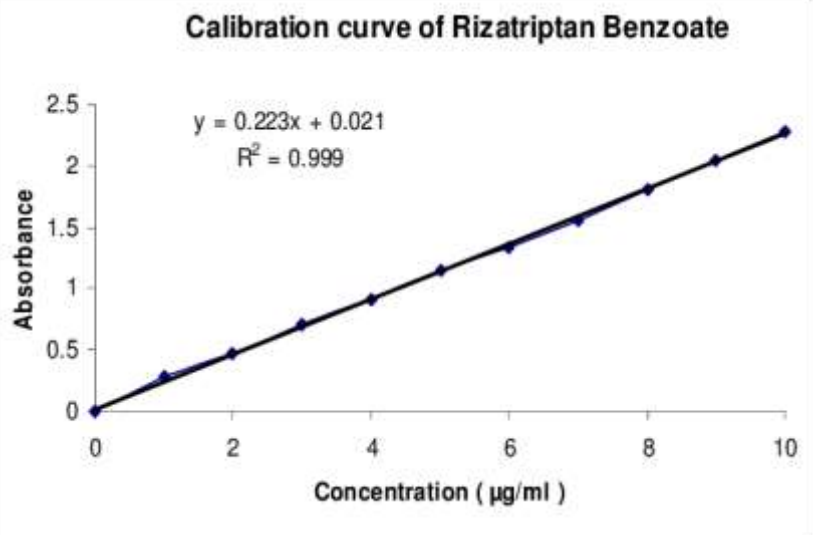

Fig: 2 Calibration curve of Rizatriptan Benzoate.

FTIR Spectroscopy:- Figure 3 shows the FTIR spectrum of pure Rizatriptan benzoate, and Table 6 provides the interpretation of these spectra. All of the peaks in the Fourier transform infrared (FTIR) spectrum of Rizatriptan benzoate were assigned to the functional groups that are present in its structure.

Table 6:- Interpretation of FTIR Spectrum ofRizatriptan Benzoate

Peak observed (cm^{-1})	**Interpretation**
3446	-NH stretching
2947	-CH3 stretching
2893	-CH2 stretching
1608	-C=C stretching
1506	-C=N stretching
1570	-NH bending
1458	-CH2 bending
1375	-CH3 bending
1296	-C-N stretching
1140	
1016	

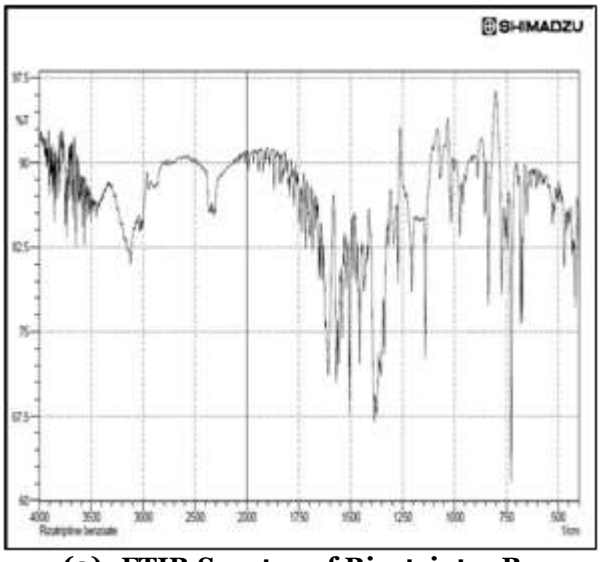

Figure (3): FTIR Spectra of RizatriptanBenzoate.

EVALUATION OF TABLETS :-

Tablets were prepared by direct compression technique.

Table 7: Data of Pre-formulation Study:

Formulation	Bulk density (gm/cm^3)	Tapped density (gm/cm^3)	Hausner's ratio	Carr's index (%)	Angle of repose
F1	0.40	0.41	1.10	10.05	31.54
F2	0.35	0.38	1.07	07.94	27.71
F3	0.36	0.35	1.06	09.11	25.60
F4	0.40	0.33	1.11	14.75	26.47
F5	0.33	0.40	1.08	09.53	28.90
F6	0.37	0.34	1.08	09.53	28.92
F7	0.36	0.32	1.07	10.54	26.43
F8	0.38	0.34	1.10	09.34	26.72

Because the material was free-flowing and die-filled uniformly, all of the formulations' tablets were able to meet the norms for weight uniformity that were required by the pharmacopoeia. The tablet hardness of the compositions is kept within the range of three to four kilograms per square centimeter. It was determined that tablets had a good mechanical resistance when the formulation had friability values that were lower than one percent. The amount of substance that was tested was within the permissible range, which was between 95% and 105%.

Table 8 Evaluation of directly compressible orally disintegrating tablets

Formulation	Wt. variation (%)	Hardness (kg/cm^2)	Friability (%)	Thickness (mm)	Wetting time (s)	Water absorption ratio (%)	Disintegrant time (s)	*in-vitro* dispersion time (s)	Assay (%)
F1	4.50	4.2	0.82	3.20	32	79.90	58±1.2	52±1.0	97.70
F2	4.00	3.6	0.85	3.14	22	82.25	56±1.2	48±1.2	98.22
F3	4.20	3.9	0.74	3.23	19	83.34	46±1.4	42±1.0	96.40
F4	3.56	3.2	0.45	3.15	18	85.76	43±1.3	40±1.3	98.42
F5	3.76	3.4	0.35	3.20	16	88.57	40±1.2	32±1.1	97.50
F6	3.56	3.2	0.36	3.22	16	92.72	36±1.6	31±1.2	97.40
F7	3.96	3.8	0.42	3.14	14	93.20	32±1.2	28±1.2	98.33
F8	3.00	3.2	0.42	3.10	13	99.00	20±1.4	15±1.2	99.40

Dissolution profile:-

Table 9 Cumulative drug release (%) [CDR] of all formulation

Sr.no.	Time (minute)	F1	F2	F3	F4	F5	F6	F7	F8
1	0	0	0	0	0	0	0	0	0
2	1	86.85	86.65	85.86	87.30	90.46	94.89	90.87	97.85
3	2	88.49	88.20	89.49	89.40	93.89	97.93	94.60	99.60
4	3	95.71	94.71	95.24	93.60	96.98	99.78	97.86	--
5	4	97.52	97.04	96.52	96.46	99.87	--	99.43	--
6	5	98.52	98.85	98.40	98.97	--	--	--	--
7	10	99.98	--	--	--	--	--	--	--
8	20	--	--	--	--	--	--	--	--
9	30	--	--	--	--	--	--	--	--

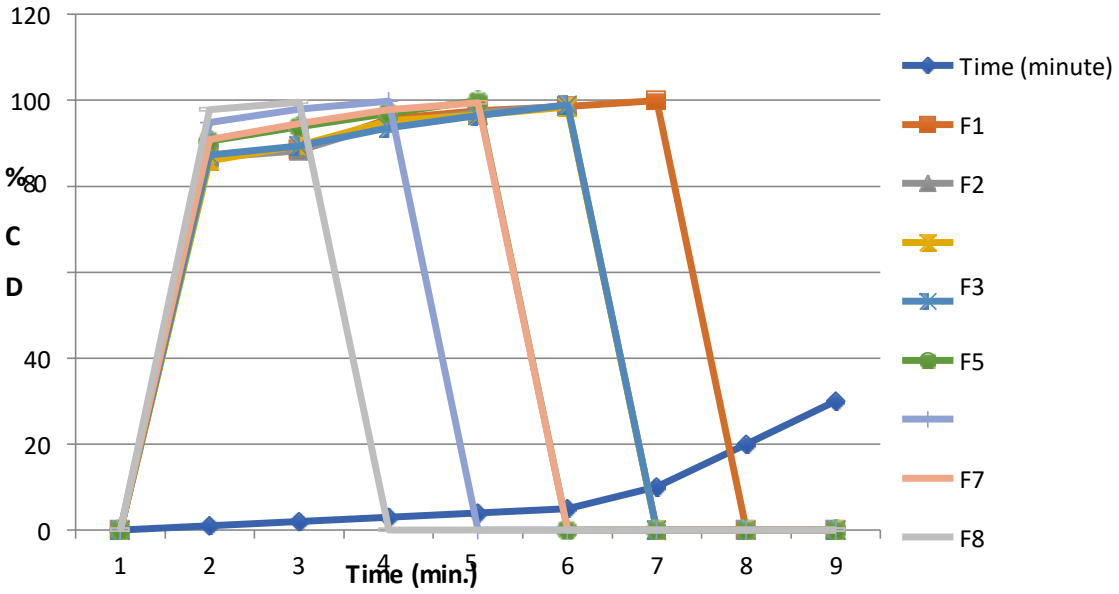

Fig. (4): Cumulative drug release(%[CDR] of all formulation.

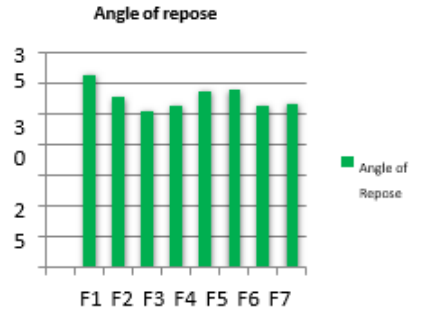

Fig. (5): Comparison of Angle of repose

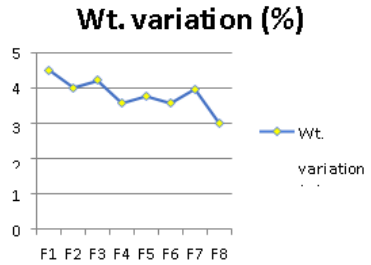

Fig. (6): Comparison of wt. variation

Fig:7 Comparison of Friability (%)

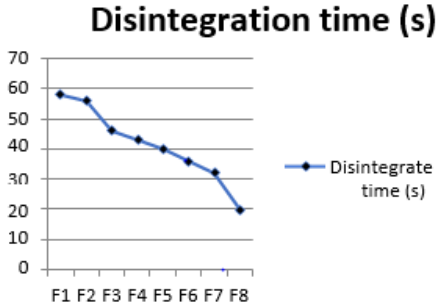

Fig.: (8) Comparison of wetting time(s)

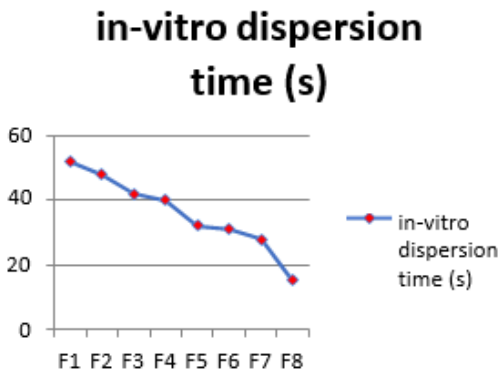

Fig.:9 Comparison of in-vitro dispersion time

VALIDATION PARAMETERS :-

Accuracy (Recovery Test): In order to establish the applicability and reproducibility of the procedure, recovery studies were carried out. These investigations consisted of augmenting the tablet with known amounts of standard Rizatriptan benzoate (concentrations of 80%, 100%, and 120%), and then evaluating the mixtures using the method that was provided. A total of three samples were taken at each stage of the recovery process. According to the data presented in Table 11, the percentage recovery of Rizatriptan benzoate was 99.7169 ± 0.7532%. This indicates that the method is not influenced by the excipients or any other factors.

Table 10 Calibration curve of Rizatriptan Benzoate

Sr. no.	ncentration (µg/ml)	Absorbance	standard deviation
1	0	0	0
2	1	0.2763	± 0.01695
3	2	0.4676	± 0.01364
4	3	0.7083	± 0.00825
5	4	0.9149	± 0.01014
6	5	1.1441	± 0.00699
7	6	1.3439	± 0.00416
8	7	1.5565	± 0.00654
9	8	1.8086	± 0.01402
10	9	2.0412	± 0.00121
11	10	2.2827	± 0.00195

Precision: Six test samples of Rizatriptan benzoate were analysed in order to determine the intra-day precision of the medication. By analysing the samples of Rizatriptan benzoate on various days and by two different analyzers working in the same laboratory, the intermediate precision, also known as the inter-day precision, of the procedure was found. On the other hand, the values for the relative standard deviation (RSD) and the assay are respectively 99.668% and 0.8554 and 98.563% and 1.0603 (Table 13).

Linearity:

The greatest absorption of rizatriptan benzoate is observed at 225 nm, and it complies with Beer's law whenever the concentration is between 1 and 10 µg/ml. The equation y = 0.223x + 0.021 for absorbance versus concentration was obtained by linear regression, and the correlation coefficient was found to be 0.999.

Limit of Detection & Limit of Quantification:

The limits of detection (LOD) and limits of quantification (LOQ) of Rizatriptan benzoate were established by employing the slope technique and the standard deviation of the response, as outlined in the recommendations established by the International Conference on Harmonisation (ICH).7 The limits of detection (LOD) and limits of quantification (LOQ) were determined to be 0.31 µg/ml and 0.94 µg/ml, respectively. Rizatriptan benzoate was determined using the suggested method, which demonstrated a molar absorptivity of 1.619Ao and Sandell's sensitivity of 8 0.004305 µg/cm2 /0.001 absorbance units.

Table 11 Validation parameters

Sr. no.	Parameter	Result
1	Absorption maxima (nm)	225
2	Linearity Range (µg/ml)	1-10
3	Standard Regression Equation	y = 0.223x + 0.021
4	Correlation Coefficient (r2)	r2 = 0. 999
5	Molar absorptivity	1.619 A°
6	A (1% 1cm)	233.13
7	Accuracy (% recovery ±SD)	99.7169 ± 0.7532%
8	Precision (%)	99.668, 98.563
9	Specificity	A 5ug/ml solution of drug in 0.1N HCl at UV detection lambda of 225 nm shows an absorbance value of 1.1441± 0.00699
10	s Sensitivity8 (ug/cm2/0.001 absorbance unit)	0.004305
11	LOD µg/ml)	0.31
12	LOQ (µg/ml)	0.94

Table 12 Determination of Accuracy by percentage recovery method

Ingredients	Tablet amount (µg/ml)	Level of addition (%)	Amount added (µg/ml)	Amount recovered (µg/ml)	% recovery	Average recovery %
Rizatriptan benzoate.	5	80	4	8.8967	98.8531	99.7169 + 0.7532%
	5	100	5	10.0236	100.2368	
	5	120	6	11.0067	100.0609	

Table: 13Determination of Precision

Sample number	Assay of rizatriptan benzoate as % of amount	
	yst-I (Intra-dayprecision)	rst-II (Inter-dayprecision)
1	99.842	97.360
2	98.190	97.124
3	100.323	99.493
4	100.559	99.431
5	99.860	98.732
6	99.239	99.239
Mean	99.668	98.563
Std. deviation	0.8554	1.0603

Conclusion

The findings indicate that the optimised orally disintegrating tablets of Rizatriptan, which contained 9.4 mg of C.P. and 8.32 mg of P.M. and were administered as a super disntegrant by the direct compression method, exhibited reactions that were in accordance with our expectations.

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